

**510(k) SUMMARY**

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K020450."

Submitter: Maine Standards Company  
Address: 765 Roosevelt Trail  
Windham, ME 04062  
Telephone: 207-892-1300  
Fax: 207-892-2266  
Contact: Christine Beach, Mgr. RA/QA

Summary prepared on: February 6, 2002

Proprietary Name: VALIDATE Chem 8 Calibration Verification Test Set  
Common Name: Calibration Verification  
Classification Name: Calibrator, Multi-Analyte

**Predicate Device:**

**DOCUMENT** Direct ISE CAL-VER, K881773, manufactured by CASCO  
NERL Diagnostics.

**Device description:** VALIDATE Chem 8 Calibration Verification Test Set contains purified chemicals in an aqueous base. Multiple levels are provided to establish the relationship between theoretical operation and actual performance of each of the included analytes. Each set contains one bottle each of five (5) levels. Each bottle contains 3.0 milliliters.

**Intended use:** VALIDATE Chem 8 Calibration Verification Test Set is intended for *in vitro* diagnostic use for quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated chemistry systems employing direct ion selective technology to measure the following analytes: lithium, sodium, potassium, and chloride.

Comparison of VALIDATE Chem 8 Calibration Verification Test Set to the predicate devices:

Table 1 compares characteristics of the VALIDATE Chem 8 Calibration Verification Test Set with those of DOCUMENT Direct ISE CAL•VER.

**TABLE 1.** Comparison of Products

	<b>VALIDATE CHEM 8 Calibration Verification Test Set</b>	<b>DOCUMENT Direct ISE CAL•VER</b>
<b>Catalog #</b>	108	M-101
<b>Intended Use</b>	For <i>in vitro</i> diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For <i>in vitro</i> diagnostic use in the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.
<b>Analytes</b>	Li, NA, K, CL	Li, NA, K, CL
<b>Matrix</b>	aqueous	aqueous
<b>Number of Levels</b>	5	5
<b>Preparation</b>	Liquid, ready to use	Liquid, ready to use
<b>Packaging</b>	3.0 mL each level	10.0 mL each level
<b>Stability</b>	Until Expiration	Until Expiration
<b>Storage</b>	2-8°C	18-25°C

The performance of VALIDATE Chem 8 Calibration Verification Test Set solutions on the AVL 9180 Electrolyte Analyzer, AVL Scientific Corporation, Roswell, GA, for lithium, sodium and potassium and the Beckman Synchron CX, Beckman Coulter, Inc. Fullerton, CA, for chloride as compared to DOCUMENT Direct ISE CAL•VER has been shown to be substantially equivalent using pre-production lots of VALIDATE Chem 8 Calibration Verification Test Set. The results of correlation comparisons between the VALIDATE Chem 8 Calibration Verification Test Set and the predicate devices are presented in Table 2.

**TABLE 2.** Linear Regression Statistical Comparison of VALIDATE Chem 8 Calibration Verification Test Set to the predicate devices.

Analyte	VALIDATE Chem 8 Calibration Verification Test Set		DOCUMENT Direct ISE CAL•VER	
	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)
Li	1.0	$1.0011x - 0.0102$	1.0	$1.0162x - 0.0685$
NA	1.0	$x + 0.0867$	0.9999	$1.0437x + 0.1$
K	0.9999	$1.0004x - 0.0607$	0.9999	$1.1243x - 0.2693$
CL	0.9998	$1.0047x - 0.0248$	0.9996	$0.9601x + 7.5$

**Summary:**

Linear regression analysis was carried out on recovered values for each analyte. Each analyte was tested in triplicate. The VALIDATE Chem 8 Calibration Verification Test Set has been shown to be functionally equivalent for calibration verification and linearity assessment to DOCUMENT Direct ISE CAL•VER.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAR 21 2002

Ms. Christine Beach  
Manager, QA/RA  
Maine Standards Company  
765 Roosevelt Trail – Suite 9A  
Windham, ME 04062

Re: k020450  
Trade/Device Name: VALIDATE Chem 8 Calibration Verification Test Set  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality control material (assayed and unassayed)  
Regulatory Class: Class I, reserved  
Product Code: JJY  
Dated: February 6, 2002  
Received: February 11, 2002

Dear Ms. Beach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized "S" and "G".

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory-Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number: K020450

Device Name: VALIDATE Chem 8 Calibration Verification Test Set

### Indications for Use:

The VALIDATE Chem 8 Calibration Verification Test Set is used by trained laboratory professionals for quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated chemistry systems employing direct ion selective technology to measure the following analytes: lithium, sodium, potassium and chloride.

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### Concurrence of CDRH, Office of Device Evaluation (ODE)

✓  
Prescription Use  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

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(Division Sign-Off)

Division of Clinical Laboratory Devices

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